SCARIFICA BETTER THAN HOPE

Amendments to DISC, TRAN and CLIN Concept Proposals
Science Subcommittee

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Background

- CIRM's Governing Board, the ICOC, approved changes to the DISC, TRAN and CLIN concepts to effectively relaunch these core programs starting January 2021 under Proposition 14.
- At this time, we are bringing some additional changes to ensure some consistency among these concepts and to remove some unnecessary barriers to applicants.
- Later this year, we expect to bring additional and more comprehensive changes that will align the concepts with a new strategic plan.

Global Changes to DISC, TRAN and CLIN Concepts

- Addition of a statement that addresses how these programs
 provide a unique opportunity to support stages of research that are
 unlikely to receive timely or sufficient funding from other sources.
- Correspondingly, remove statements in eligibility section that require applicants to demonstrate that they are unlikely to receive timely or sufficient funding from other sources.
- Broadly include gene therapy projects as in-scope for CIRM funding for diagnostic, device, and tool projects.

Global Changes to DISC, TRAN and CLIN Concepts

- Remove eligibility requirement that small molecule/biologics proposals must involve a therapeutic candidate previously funded by CIRM.
- Minor clarifications and adding "regenerative medicine" to broadly describe scope of CIRM funding.

Proposed Changes to DISC2 Program

Discovery awards to identify a candidate therapeutic, medical device, diagnostic, or tool

• Minor clarifications in the description of eligible gene therapy candidates

Proposed Changes to TRAN Program

(TRAN1, TRAN2, TRAN3, TRAN4)

Translational awards to advance a candidate therapeutic, medical device, diagnostic, or tool to the clinic or commercialization.

- Change Project Manager percent effort requirements to 50% (prev. 35%)
- Addition of gene therapy to scope of diagnostic (TRAN2), medical device (TRAN3), and tool (TRAN4) projects

Proposed Changes to CLIN Program (CLIN1, CLIN2, CLIN3)

Awards to support IND-enabling activities and clinical trials

- Change time to IND filing in CLIN1 from 18 to 24 months
- Change percent effort requirement for project manager to 50% for CLIN1 (prev. 75%)
- Remove preference for rare or pediatric indications for phase 3 trials

Requested Action

CIRM requests the Science Subcommittee recommend Board consideration of the proposed amendments to the DISC, TRAN, and CLIN concept plans.